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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
Atlanta GA 30333

SEP 9 1982

Docket Officer
U.S. Department of Labor
OSHA Docket Office (Docket No. H-022)
Room SG212
Third Street and Constitution Ave., N.W.
Washington, DC 20210

Dear Sir:

Enclosed are the post-hearing comments submitted by NIOSH in response to requests made by the Department of Labor at the Hazard Communication Public Hearing of June 15, 1982.

These comments address the following:

1. Specific recommendations to OSHA for better definition of terms, such as carcinogenicity and definitions of health hazards, particularly where use of external documents could be required, and;

2. Information from the National Occupational Hazard Survey (NOHS-I) on the distribution of chemical exposures in SIC codes 20 through 39.

Sincerely yours,

J. Donald Millar /sc

J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

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POST-HEARING COMMENTS
Submitted to OSHA Docket H-022
by the
National Institute for Occupational Safety and Health
August 9, 1982

In any standard requiring chemical manufacturers and employees to evaluate chemicals produced or used, the chief question is how a hazard is defined. The OSHA proposed rule on Hazards Communication attempts to make such definitions in Appendices A and B (47 FR 12122-3).

The NIOSH testimony presented on 15 June 1982, expressed a concern that a lack of detailed guidelines for such definitions could undermine the effectiveness of the proposed rule. The often conflicting scientific data in the literature, as well as, the constantly changing data base of scientific information complicates the assessment of a substance's hazard potential. The NIOSH testimony emphasized that selective or biased interpretations of the scientific literature could lead to wide variations in the Labels and Material Safety Data Sheets. Competition for product sales based on differing rigor of hazard determinations could develop. The trade secret provisions of the proposed rule could hide biased hazard determinations from even the most conscientious downstream employer.

Strict definitions of carcinogenicity, mutagenicity, and teratogenicity are difficult to arrive at with the scientific community itself not in agreement. An approach that can be taken in providing guidance to such inquiries, would be to investigate where groups of scientists have arrived at some kind of consensus, or where Federal agencies have made considered determinations on these definitions. We believe that four such sources exist for providing assistance in arriving at determinations of carcinogenicity, teratogenicity, mutagenicity or simply, what can represent a "hazard" for purposes of compliance.

NIOSH in its testimony, suggested that consultation of certain documents be made mandatory to ensure a "floor" to the depth of inquiry to a products' degree of hazard.

NIOSH believes that certain documents by themselves represent a scientific consensus as to a particular chemicals' carcinogenicity, mutagenicity or teratogenicity. In our testimony, we suggested that the following documents be required to be consulted in evaluating hazards:

1. National Toxicology Program Annual Report on Carcinogens;

2. NIOSH Criteria Documents, Current Intelligence Bulletin's (CIBs) and other documents presenting Institute recommendations;

3. OSHA regulations, and;

4. the American Conference of Governmental Industrial Hygienists (ACGIH), Threshold Limit Values and their documentation.

The following descriptions of the documents emphasize their suitability for the determination of minimum hazard communication needs.

The Annual Report on Carcinogens prepared by the National Toxicology Program of the U.S. Public Health Service, is issued by the Department of Health and Human Services. This Report is published pursuant to Public Law 95-622, which mandates an annual report which contains " . . . a list of all substances (i) which either are known to be carcinogens or which a significant number of persons residing in the United States are exposed . . ." .

The fact that a substance is not included in the Annual Report, does not mean that it is not a confirmed or suspected carcinogen. Some chemicals are included that have been banned or whose use has been restricted because there are people who were previously exposed that are potentially at risk, or because some of these chemicals remain in the environment.

This Annual Report includes known human carcinogens and substances which may reasonably be anticipated to cause concern in humans. Public Law 95-622 does not require scientific proof of human or animal carcinogenicity for a substance to be included on the list, or a precise elucidation of its mechanisms of action. When there is sufficient evidence that a substance causes cancer in animals, then that substance is also included by NTP in the Annual Report.

Chemicals included in the Annual Report are chosen from those previously evaluated by the International Agency for Research on Cancer (IARC), or selected on the basis of positive findings from the bioassay reports of the National Toxicology Program/National Cancer Institute Carcinogenesis Testing Program or have been suggested by an agency participating in the National Toxicology Program. These participating agencies are the National Institute for Occupational Safety and Health, Consumer Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, National Cancer Institute, National Institute of Environmental Health Sciences and the Occupational Safety and Health Administration. The current Annual Report is available from the Public Information Office, National Toxicology Program, MD B2-04, P. O. Box 12233, Research Triangle Park, North Carolina 27709.

NIOSH Criteria Documents make recommendations to OSHA for standards and present a complete collection of scientific data and evaluations of the toxicity or carcinogenicity of a chemical. NIOSH also publishes Current Intelligence Bulletins which serve as an early warning mechanism to alert the occupational safety and health community to emerging problems. Both documents present the position of NIOSH relative to a particular chemical's hazard.

Standards promulgated by OSHA by definition, are conclusive to a substance's carcinogenicity or toxicity.

The Threshold Limit Values (TLV's) published by the American Conference of Governmental Industrial Hygienists, represent concentrations of substances and conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect. These TLV's are

based on the best available information from industrial experience, from experiments and human and animal studies. These TLV's are established by a Threshold Limit Values Committee made up of recognized experts in the field. The TLV documentation provides the rationale for the inclusion of a substance in TLV list.

The American Conference of Governmental Industrial Hygienists is a professional, non-governmental organization having as its purpose, the development of administrative and technical aspects of worker health protection.

These four resources are not meant to be an all-inclusive listing. The point should be made that a listing of recognized sources of toxicity information would go a long way to establish a minimum duty of inquiry on employers and producers and establish a "floor" for which a minimum inquiry is required.

NIOSH also submits to the record NOHS I data, showing the number of products encountered in facilities surveyed in SIC codes 20 through 39. These figures represent a measure of potential exposure to chemicals. As can be noted in our testimony, employees in these industries warrant protection from the variety of products encountered in their workplaces.

TABLE I

Average Number of Products Used per Facility

NOHS I

SIC Code	Name	# Facilities Surveyed	Average # Products/Facility
20	Food & Kindred Products	166	13.9
21	Tobacco Manufacturers	18	17.5
22	Textile Mill Products	74	22.6
23	Apparel & Other Finished Products	96	6.7
24	Lumber & Wood Products	60	10.8
25	Furniture & Fixtures	141	13.8
26	Paper & Allied Products	122	29.0
27	Printing, Publishing	138	31.3
28	Chemicals & Allied Products	110	45.1
29	Petroleum Refinishing	44	31.8
30	Rubber & Miscellaneous Plastic	182	27.1
31	Leather & Leather Products	69	23.8
32	Stone, Clay, Glasses, & Concrete	117	26.7
33	Primary Metal Products	142	25.2
34	Fabricated Metal Products	344	15.7
35	Machinery	261	18.2
36	Electrical & Electronic Machinery	170	25.1
37	Transportation Equipment	106	41.0
38	Instruments, etc.	93	27.3
39	Miscellaneous Manufacturing Industries	140	21.4